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| 10/560,652 | 05/30/2006 | Joanne Chory | 532792000800 | 9156 |

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| EXAMINER |
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BAUM, STUART F

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| ART UNIT | PAPER NUMBER |
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1638

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04/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/560,652 | Applicant(s) CHORY ET AL. | |
| | Examiner STUART F. BAUM | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 29-37 is/are pending in the application.
- 4a) Of the above claim(s) 14-22 and 37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 1-13, 23, 24, 27 and 29-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 1/28/2009 has been entered.
2. Claims 1-27 and 29-37 are pending.

Claims 28 and 38 have been canceled.

Claims 14-22 and 37 have been withdrawn from consideration for being drawn to non-elected inventions.
3. Claims 1-13, 23-27 and 29-36, including SEQ ID NO:2 encoding SEQ ID NO:3 are examined in the present office action.
4. Rejections and objections not set forth below are withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Restriction Requirement

6. Applicants contend the special technical feature of the invention is in part a PFT1 protein wherein the PFT1 protein has an amino acid sequence at least 45% identical to SEQ ID NO:3 (page 9 of Remarks, 2nd full paragraph).

The Office contends Lin et al (2001, NCBI Accession Number AC079281) disclose a protein that exhibits 83% identity with Applicants' SEQ ID NO:3 (see sequence search results attached with the previous office action mailed 10/28/2008) and therefore the special technical feature is taught in the prior art and the restriction is maintained.

Scope of Enablement

7. Claims 1-13, 23-24, 27 and 29-36 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant nucleic acid sequence comprising SEQ ID NO:2 or comprising a nucleotide sequence encoding SEQ ID NO:3, and expression vector comprising said recombinant nucleic acid operably linked to a promoter and transgenic plant comprising said vector wherein the plant has an early flowering phenotype compared to a wild-type plant and a method for decreasing flowering time in a plant comprising transforming a plant with said vector, does not reasonably provide enablement for any nucleic acid sequence exhibiting less than 100% sequence identity to SEQ ID NO:2 or any nucleic acid sequence encoding a protein exhibiting less than 100% sequence identity to SEQ ID NO:3 and plant transformation therewith or any method comprising said nucleic acid sequence or any method of modulating at least one photosensitive trait in a plant comprising said nucleic acid sequence or wherein said sequence encodes SEQ ID NO:3 or wherein said sequence comprises SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/28/2008. Applicant's arguments filed 1/28/2009 have been fully considered but they are not persuasive.

Applicants have addressed the enablement rejection by reviewing the Wands factors as they apply to the instant claims. Applicants contend the amended claims are not unduly broad (paragraph bridging pages 12 and 13 of Remarks).

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The Office contends Applicants are enabled for SEQ ID NO:2 or for a nucleic acid encoding SEQ ID NO:3. The Office contends given an evaluation of the Wands factors, the Office has determined the claims as written are not enabled. The Office contends the claims are broadly drawn in part to methods, plants or an isolated nucleic acid comprising any nucleic acid that hybridizes to SEQ ID NO:2 under conditions specified in claim 1 or nucleic acid molecules encoding a protein exhibiting at least 45% sequence identity to SEQ ID NO:3 or a nucleic acid molecule that has at least 90% identity to SEQ ID NO:2. Applicants have not disclosed a nucleic acid encoding a polypeptide that has at least 45% sequence identity to SEQ ID NO:3 and is operable in Applicants' invention. Applicants have also not specified a functional limitation that distinguishes those proteins with the proper activity from proteins that do not have the proper activity.

Applicants contend the disclosed sequences combined with the knowledge in the art of methods for analyzing sequence structure for conserved regions and domains provide a high degree of predictability that will provide one of skill in the art with a starting point. Applicants contend Figure 9 discloses amino acid sequences from other plant species that have less than 100% sequence identity to SEQ ID NO:3, but that are still identifiable as PFT1 proteins (page 13 of Remarks, 3rd full paragraph).

The Office contends Applicants' claims encompass nucleic acid molecules that do not possess the required activity to be operable in Applicants' invention. The Office contends the alignment aids in providing guidance as to which amino acids are necessary but Applicants have not disclosed if all of the recited proteins are operable in Applicants' invention especially since the state-of-the-art teaches that protein prediction is unpredictable.

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Applicants contend the specification teaches how to make the claimed nucleotide sequences (page 15 of Remarks, 1st full paragraph). Applicants contend paragraph [0084] of the published application describes a method of generating a genetically modified plant having altered flowering time by contacting a plant cell with at least one expression vector containing the nucleic acid of interest to obtain a transformed plant cell, producing a plant from said transformed cell, and selecting a plant exhibiting altered flowering time. Plants that express any of the instantly claimed nucleic acids can be screened for altered flowering time, and can thus be identified by comparing the flowering time of the transformed plant to the flowering time of wild type plants by visual observation as described, for example, at paragraph [0116] (page 16 of Remarks, 1st paragraph).

The Office contends Applicants have only exemplified one sequence. The MPEP states "In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (see MPEP 2164.03). See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), which teaches that the allegedly pioneering nature of an invention does not obviate the need for "a reasonable correlation" between the scope of the claims and "the scope of enablement provided by the specification", wherein "the scope of enablement obviously varies conversely with the degree of unpredictability of the factors involved" in "cases involving unpredictable factors, such as most chemical reactions and physiological activities".

Applicants contend methods for altering the level of proteins in an organism are well known in the art (page 17 of Remarks, 3rd full paragraph). Applicants contend that none of the instantly pending claims require that the isolated DNA fragments have contiguous nucleotide

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sequences that are the same or nearly the same as the probe. They only require that the fragments hybridize to SEQ ID NO:2 under the specified conditions (page 18 of Remarks, 1st full paragraph).

The Office contends that not all fragments that hybridize to SEQ ID NO:2 will encode a polypeptide with the requisite activity to be operable in Applicants' invention, especially in light of a lack of a functional limitation as discussed above.

Applicants contend that the state of the art is such that many routine methods are available to one of skill in the art to identify and screen which of the sequences that hybridize to SEQ ID NO: 2 under very high stringent wash conditions would retain PFT1 activity (page 18 of Remarks, 2nd full paragraph). Applicants contend the quantity of experimentation is not undue because the described experimentation is routine for those of skill in the art (page 19 of Remarks, 1st paragraph). Applicants contend Example 2 of the instant specification shows how the gene encoding PFT1 was cloned and expressed in plants (page 19 of Remarks, 2nd paragraph). Applicants contend the instantly claimed invention only requires routine molecular biology techniques and the level of skill in the art is quite high (page 19 of Remarks, 3rd and 4th paragraphs).

Claim 1 as currently amended is drawn to a method of modulating at least one photosensitive trait comprising altering the level of PFT1 protein in a plant, wherein said PFT1 is encoded by a nucleotide sequence hybridizing to SEQ ID NO:2 under conditions specified in the claim or wherein the amino acid sequence has at least 45% identity to SEQ ID NO:3. The recitation of a polypeptide with at least 45% amino acid sequence identity to SEQ ID NO:3 represents a partial structure. That is, the claimed polypeptides share at least 45% of the structure

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of SEQ ID NO:3, while 55% of the structure can vary. There is no teaching in the specification regarding which 55% of the structure of the polypeptide can be varied while retaining the required activity to produce plants that flower early when the protein of SEQ ID NO:3 is overexpressed (page 33 of the specification, top paragraph). Further, there is no art-recognized correlation between any structure, other than SEQ ID NO:2 of the instant application, and the required activity to produce early flowering based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 2 without losing the catalytic activity. Consequently, there is no information about which amino acids can vary from SEQ ID NO:2 in the claimed genus of polypeptides and still retain the required activity. The Office contends Applicants have not disclosed other PFT1 proteins from other plants that have the same activity when transformed into a plant and Applicants have not modulated any photosensitive trait other than flowering time.

The Office contends, given the state-of-the-art and unpredictability of predicting protein structure as discussed previously, and given the unpredictability of selecting DNA fragments that encode a protein with the desired activity, and given the lack of disclosure for a structure/function relationship as discussed above, and given the lack of teaching for using a plant transformed with a DNA sequence that does not have the requisite activity and given the breadth of the claims, undue trial and error experimentation would be required by one of skill in the art to make and use the claimed invention.

8. Claims 1-13, 23-27 and 29-36 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:25 encoding

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SEQ ID NO:3 or method of decreasing flowering time comprising transforming a plant with an expression vector comprising a nucleic acid molecule that hybridizes to SEQ ID NO:2 under conditions specified in claim 7 or encodes a protein having at least 45% sequence identity to SEQ ID NO:3.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
April 6, 2009